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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,454	02/02/2001	Gregorio del Val	2001-0705	9327

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,454	VAL ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/11/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10,12,22-25,27-35 and 37-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-8, 10, 12, 22-25, 27-35, and 37-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1-4, 6-8, 10, 12, 22-25, 27-35, and 37-47 are pending.

Applicants' traversal, the amendment of claims 1, 4, 6, 8, 12, 22, 25, 27, 29, 31, 32, 35, 37, 39, and 41 and the addition of claims 42-47 filed on 8/18/04 is acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8, 10, 12, 22-25, 27-35, and 37-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'a dog' in amended claims 1, 22, and 32 and claims dependent therefrom is not supported by the as-filed specification. Applicant has not pointed out where the amended claims are supported, nor does there appear to be a written description of the claim limitation 'a dog' in the application as filed. See MPEP § 2163.06. The specification provides support for an atopic dog (see originally filed claims).

In addition, amended claims 1, 22, and 32 and claims dependent therefrom, including new claims 42-47 filed on 8/11/04 introduce new subject matter into the application. The application and the originally filed claim as a whole are directed to:

A method for testing the allergenicity of a heterologous protein produced by a plant or animal that has been genetically modified to produce that protein, comprising the steps of:

(a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant or animal and containing a mixture of plant or animal proteins a d the heterologous protein, by injecting, feeding or applying the extract to the skin of e newborn dog,

(b) after a period sufficient to allow the dog to establish an immune response to the sensitizing extract, challenging the dog with the extract,

(c) observing the degree of allergic response provoked,

(d) if a detectable skin reaction is observed, comparing the degree of skin reaction observed with that observed by carrying out steps (a)-(c) above, but where the sensitizing step (a) or applying step (b) is carried out with a second plant or animal extract containing substantially the same proteins as the first extract but lacking the heterologous protein, and

(e) if the degree of skin reaction at (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans.

The amended claims are not supported by the original specification, as described above, the specification did not disclose using a dog in the claimed methods. The term "a dog" is broader than the atopic dog disclosed in the specification.

Furthermore, the amended claims no longer have steps d)-g), only d) and e) and the dog used in the second part of the assay may or may not be the same dog as in step a). As set forth above in the original claims and specification, the claims support using an atopic dog in steps a) and d), wherein the atopic dog in step d) is a different atopic dog than the atopic dog used in step a). The specification contemplates the method set forth above in the originally filed claims, wherein a dog from an atopic colony is sensitized and challenged with a first extract from tissue of a genetically modified plant containing a mixture of plant proteins and a heterologous protein and if a degree of allergic response is provoked then a dog from an atopic dog colony is sensitized to a second plant extract containing the same proteins as the first extract, but lacking the heterologous protein (page 5). The working examples in the specification are directed to using atopic dogs in a method of sensitizing and challenging and does not contemplate or recite the steps d)-e) of the claimed method. It is apparent that the applicants at the time the invention was made did not intend or contemplate using a dog in the claimed method as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the method as set forth in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments filed 8/11/04 have been fully considered but they are not persuasive.

Applicants argue that Example 2, Table 2 on page 24, and page 20, lines 7-29 contain clear example of the use of the same dog for the subsequent steps d-e.

Applicants' argument is not found persuasive because Example 2 does not teach using a second extract. Based on the examiner's reading of Example 2, here is an outline of the protocol of Example 2: two groups (7FB and 7FC) were immunized with food extract, including transgenic corn. Next, 7FB was sensitized to peanut. Then, 7FB was sensitized to barley and 5 from 7FC were sensitizes to barley and 4 were sensitized to Brazil nut. 7FA was sensitized ragweed, wheat, and soy. There is nothing in the specification to indicated that 7FA, 7FB, and 7FB were a) sensitized to a heterologous protein and transgenic plant mixture; b) challenged with the heterologous protein and transgenic plant mixture; and c) comparing the degree of allergic response to a dog challenged with a second extract but lacking the heterologous protein.

Applicants further argue that page 6, lines 21-25 of the specification where the same dog is challenged with both the control substance (the second extract) and the test extract (the first extract).

Applicants' argument is not found persuasive because there is no mention of a second extract on page 6.

Claims 3, 24 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 3, 24, and 34 filed on 8/11/04 introduce new subject matter into the application. The application and the originally filed claim as a whole are directed to a method of testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein comprising using a first extract comprising a mixture of plant proteins and the heterologous protein and a second extract comprising the same proteins as the first extract, but lacking the heterologous protein.

The original specification did not disclose using a second extract obtained from a genetically modified plant in the challenging step. The specification teaches using a genetically modified plant in the sensitizing step. The specification recites, "in a preferred embodiment, the extract is obtained from a transgenic plant (page 5, lines 24-25)" and "The second type of extract is prepared from tissue of a genetically modified plant or animal and contains a mixture of plant or animal proteins (page 12, B1. Sensitizing, lines 30-34)." It is apparent that the applicants at the time the invention was made did not intend or contemplate using a second extract obtained from a genetically modified plant in the challenging step as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of using a second extract obtained from a genetically modified plant in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments filed 8/11/04 have been fully considered but they are not persuasive.

Applicants argue that the language in the original claim used a "second plant extract containing substantially the same proteins but lacking the heterologous proteins." Thus in the

original claims, the definition of the second extract did not distinguish between transgenic and non-transgenic plants as the source of the second extract and therefore clearly covered both.

With respect to applicants' argument, the argument is not found persuasive because nothing in the disclosure as filed would lead one to the particular combination set forth in the claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997). Furthermore, a genus does not anticipate a species. See MPEP 2163.

Applicants further argue that on page 6, lines 21-24, the specification discloses challenging a dog with a control extract and page 12, lines 30-34 defines a control extract as including transgenic plants.

With respect to applicants' argument, the argument is not found persuasive because the control material on page 6 refers back to a non-allergen control material. The specification does not support that the second extract is considered a control material, e.g., non-allergen control material.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4, 6-8, 10, 12, 22-25, 27-35, 37-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 22, and 32 are rejected under 112 second paragraph because of the phrase "in a dog observed after provoking by challenging in the same manner as in step (b)" is indefinite. The metes and bounds of the phrase in the claims is not defined because it is not apparent if the dog used in step (d) is: another atopic dog from the same colony as the atopic dog in step (a); same atopic dog used in step (a); a non-atopic dog, etc.

Claims 2-4, 6-8, 10, 12, 23-25, 27-31, 33-35, and 37-47 are rejected under 112 second paragraph because the claims depend from claims 1, 22, and 32.

Claims 2, 23, and 33 recite the limitation "the dog". There is insufficient antecedent basis for this limitation in the claim. There are two types of dogs (atopic dog and a dog) set forth in the claims from which these claims depend from and the disclosure does not define if either the atopic dog or the dog are being used in these steps or if the both dogs are being used in the challenging and observing steps set forth in claims 2, 23 and 33.

Conclusion

It was noted that applicants requested another interview with the examiner upon receipt and the review of the response filed on 8/11/04. Examiner contacted Otis Littlefield's office on 8/18/04 and left a message on his answering machine asking him to call the examiner back about scheduling an interview. Dr. Littlefield did not returned the examiner's call.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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